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(54) Title: ORTHOPAEDIC SPLINTING/CASTING MATERIAL

(57) Abstract

An orthopaedic splinting/casting material comprises a high molecular weight polyester in combination with a cellulosic filler, the material is mouldable at a temperature in the range of 55 to 70 °C and has a self-adherent characteristic at such temperature, its weight is in the range 0.75 to 4.0 kg/m^2, its density in the range 900 to 1200 kg/m^3, and its modulus, at ambient temperature, not less than 350 mPa. Preferably the polyester is a polyhexamethylene adipate or a polyepsilon-caprolactone. The cellulosic filler may be one or a combination of ground almond shell, ground olive stones and wood flour. Preferably the polyester is in powder form, in which case the polyester and the filler are both generally of the same or closely similar grain size distribution. If desired a fabric layer, e.g. a lightweight polyester fabric, may be incorporated at or adjacent at least one surface of the polyester/filler material.

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ORTHOPAEDIC SPLINTING/CASTING MATERIAL

TECHNICAL FIELD

This invention is concerned with orthopaedic splinting/casting materials.

BACKGROUND ART

There are described in GB-A-1 366 091 various formable orthopaedic cast materials in the form of a bandage, web, film, tape or sheet for use in the treatment of both human and animal bodies, in particular in the case of broken limbs and sprains. In the case of each of the various materials there described it is proposed to use high molecular weight poly-epsilon-caprolactone, either as a component of a blend or as a sole polymeric constituent. Poly-epsilon-caprolactone had the advantage of being easily and rapidly applicable to the affected body part when heated to a moulding temperature, while forming a rigid, non-irritating, strong, durable, water-resistant, close-fitting splint or cast when at temperatures below the softening temperature, which splint or cast was nevertheless easily removable when no longer required without risk of injury or irritation to the patient and indeed without serious damage to the material itself, which could therefore be sterilised and re-used, if desired. Because the splint or cast could be custom-made from sheet or the like, furthermore, it was not necessary to stock different sizes or styles of splint or cast. Moreover, splints or casts made from poly-epsilon-caprolactone are relatively light in weight and do not have the disadvantages of being bulky, as was the case with previously used plaster of Paris, for example. Moreover, the softening

temperature of poly-epsilon-caprolactone is in the range 55 to 70°C, which, especially bearing in mind the low thermal conductivity of the material, would not cause discomfort to the patient whose body part is brought into contact with the thus softened material.

Problems have, however, been perceived in the use of poly-epsilon-caprolactone and various proposals have been made for modifying it, and in particular for blending it with other polymeric materials, in order to achieve physical characteristics which are considered to be desired: see e.g. US-A-4,144,223, GB-A-2 015 004 and WO 83/02898.

It is of course well known that the physical characteristics of a polymer can be significantly varied by the use of fillers, which also of course in general render the cost of the material cheaper. Thus, in GB-A-1 366 091 it is proposed that up to 25% by weight filler can be used. Moreover, the proposed fillers in this case include magnesium or calcium carbonate, finely divided silica, clay, asbestos and alpha cellulose, the filler particles in each case being in a size range of 3 to 4 microns. In other proposals made, fillers having a particle size up to 50 microns have been proposed, again however of the same filler types as referred to in GB-A-1 366 091.

It is also known to provide a material for use in reinforcing/stiffening shoes, which material comprises a polyester having a molecular weight of not less than 10,000 and a viscosity measured at 100°C of at least 30 Pa.s in combination with a filler, said material being mouldable at a temperature in the range 55 to 70°C, having a weight in the range 0.75 to 1.25 kg/m^2, a density in the range 900 to 1200 kg/m^3, and a modulus, at ambient temperature, in the order of 350 to 700 mPa. One such material is described in our co-pending

EP-A-0 448 294, which material comprises a polyhexamethylene adipate of the type described, along with its manner of manufacture, in EP-A-0 448 079. In addition, there are described in EP-A-0 349 140 and EP-A-0 183 912 respectively shoe reinforcing/stiffening materials comprising a polycaprolactone.

In the last mentioned specification it is proposed to use a filler which is made wholly of or at least a surface of which is coated with a synthetic material, one preferred embodiment comprising hard PVC. In EP-A-0 349 140, on the other hand, a filler is proposed in the form of pulverised fuel ash, while in EP-A-0 448 294, in addition to the two fillers already referred to, a proposal is made to utilise almond shell grain, olive stone grain or wood flour.

In contrast with the relatively low grain size distribution of the materials disclosed in GB-A-1 366 091, the grain size distribution in each of the three EP Specifications referred to is substantially greater, being in the order of 50 to 500, preferably 100 to 400 (in the case of 0 183 912), 350 microns (in the case of 0 349 140), and up to 600 microns (in the case of 0 448 294). Thus, in the case of the reinforcing/ stiffening materials for shoes, a substantially higher grain size distribution of the filler is encountered than in the previous cases relating to splinting/casting materials.

In using a splinting or casting material based upon poly-epsilon-caprolactone, or indeed any other splinting or casting material, it is highly desirable, especially in the case of the smaller body parts, for the moulding of the material to follow closely the shape of the body part to which the splint or cast is to be applied. In addition, it is highly desirable that the "feel" of the contacting surface of the material is

comfortable to the patient. In the case of larger limbs it may be that a suitable sheet material can be interposed between the casting or splinting material on the one hand and the skin on the other, but, in particular in the case of smaller body parts, such an interlining would be detrimental to the accuracy of the moulding to the shape of the body part in question. It is thus very desirable for the surface of the material itself to have the desired "feel".

A further feature which has been found desirable, and which is closely related to the comfortable "feel" referred to above, is to ensure that sufficient ventilation is provided to the region of the skin encased by the cast or splint material. In e.g. US-A-4,240,415, therefore, it is proposed to perforate the material over the whole of its area.

OBJECT OF THE INVENTION

It is thus an object of the present invention to provide an improved orthopaedic splinting/casting material which is moisture-permeable and which has a comfortable "feel" when applied to a body part.

SUMMARY OF THE INVENTION

It has now been established that, surprisingly, the shoe reinforcing/stiffening materials are in certain circumstances, and with selected fillers, appropriate in resolving the object of the present invention. More particularly, the solution in accordance with the present invention resides in the use, as an orthopaedic splinting or casting material, of a material in sheet or strip form comprising not less than 50% by weight of a polyester having a molecular weight of not less than 10,000 and a

viscosity measured at 100°C of at least 30 Pa.s, and up to 50% by weight of a cellulosic filler, said material being mouldable at a temperature in the range 55 to 70°C, being self-adherent at such moulding temperature, and having

- a weight in the range 0.75 to 4.0 kg/m^2,
- a density in the range 900 to 1200 kg/m^3, and
- a modulus, at ambient temperature, of not less than 350 mPa.

It has been found that the use of such a material affords comfort to the wearer in terms both of the surface "feel" of the material and also by reason of the material being moisture-permeable. (Tests have shown that vapour transmission rates through the material are in the order of not less than 300 mg/m^2/hour.) The reason for the moisture-permeability is not wholly understood, but it is believed that the presence of relatively large particles of cellulosic filler, constituting up to 50% of the total weight of the polyester/filler composition, allows paths through the thickness of the material by the juxtaposition of moisture-absorbent filler particles. Moreover, it may be presumed that, based on the difference in density between the constituent parts and the overall density of the material, the material is in fact also microporous.

The stiffness of the material, which is of course a function of the thickness and modulus, depends largely upon the requirements for the particular body part to be treated. Thus, in the case of, say, a fractured limb, a heavy gauge material will be required in order totally to immobilise the limb in question. In the case of a moderate sprain, on the other hand, a much less thick (and thus a much less stiff) material will be adequate. It is likely, therefore, that materials having a thickness in the range 1 to 4mm will be adequate for

most purposes in accordance with the invention.

Suitable polyesters for use in a material as referred to above are preferably aliphatic polyesters, e.g. poly-epsilon-caprolactone (which is a polymer formed of a cyclic ester) and polyhexamethylene adipate of a type having high molecular weight, as disclosed in EP-A-0 448 079. Moreover, preferably the polyester has a molecular weight of at least 30,000 and a viscosity measured at 100°C of at least 600 Pa.s.

Preferably the material comprises not less than 55% by weight polyester; more preferably the polyester:filler ratio is in the order of 60:40.

Preferably the material incorporates a fabric layer at or adjacent at least one surface. The fabric layer is preferably a non-woven synthetic material, e.g. viscose or polyester, having a melt temperature higher than that of the polyester, in which case there is little or no tendency for the non-woven layer to soften when the polyester/filler composition is softened. Preferably, furthermore, the or each fabric layer has a weight not exceeding about 0.025 kg/m^2. When the material is in use, and especially when pressure is applied to the material in its softened state, sufficient of the polyester/filler material passes through the fabric layer to provide an adhesive surface, but the fabric layer does not become wholly embedded in the polyester/filler composition. Thus, by the provision of such a layer or layers, when the material has been heated to soften it, the effect of the layer(s) is to render the hot material more readily capable of being handled comfortably not only from the point of view of the heat in the composition, but also in reducing the tendency of the material to stick to the hands of the person handling it. Similarly, the fabric layer has the same effect in relation to the skin of the patient. Moreover, by

providing what is essentially a non-flat surface, by arranging the fabric layer(s) at or adjacent the surface of the material, an air gap is created between the material and the skin of the patient, and this air gap is believed to contribute to the comfortable "feel" of the material when in use. A further advantage of the use of a fabric layer in this manner is that it can be utilised to alter the tensile properties of the finished product; where, for example a non-woven layer is used which has been produced by carding and then bonding fibres, it significantly restrains elongation of the finished product in the "machine" direction, i.e. the direction in which the fibres are laid. In the case of e.g. spun-bonded or hydro-entangled non-woven fabrics, on the other hand, the tendency of the composition to stretch when softened can be restrained in all directions.

The cellulosic filler is preferably selected from one or a combination of the following:

- ground almond shell having a grain size distribution of 150 to 400 microns,
- ground olive stones having a grain size distribution of 150 to 400 microns, and
- wood flour having a grain size distribution of up to a maximum of 600 microns.

It will of course be appreciated by the selection of different fillers, the stiffness of the finished product can be varied. The selection of a particular cellulosic filler to be used will be determined largely according to the desired weight and stiffness of the finished product.

One significant advantage of the material referred to above has been found to be that it is substantially transparent to X-rays. Thus it is possible, while a splint made of said material remains in situ for the limb to be X-rayed without any significant increase

in the level of radiation.

A preferred manner of manufacturing the material for use as referred to above is by a powder deposition process in which the polyester in powder form is first mixed with the filler; it should of course be understood that the grain size distribution of the polyester powder should be the same as or closely similar to that of the filler in order to ensure proper mixing and to prevent separating out during dispensing of the powder. The thus mixed powder is then deposited in a measured layer on a band of non-woven fabric which passes beneath the dispensing hopper and is supported on a suitable belt and thereafter preferably a second layer of non-woven fabric is laid over the thus deposited layer and the "sandwich" is passed through a double-band press, e.g. of the type described in EP-A-0 322 145. This press serves by heating and subsequent cooling to fuse and consolidate the powder into a continuous material; if desired, a pre-heating step may be included prior to the second non-woven layer being introduced, this pre-heating step serving to cause an initial fusion of the powder materials. After the consolidated material has left the belts of the press, and while it is in a still mouldable state, it is passed between rollers by which the final thickness (gauge) of the material is determined. Thereafter the material is either formed into rolls or cut into sheets and stacked. In a different method of production, still utilising a powder deposition process, the press may be replaced by an oven, in which case the second non-woven layer may be dispensed with, while in yet another method of production two plies of material are used, one comprising two layers of a non-woven fabric with a polyester layer therebetween, as referred to above, and the other comprising a layer of polyester having a layer of non-woven fabric on one side only

thereof, the two plies being placed in face-to-face contact, with the fabric surface of the second ply exposed, and being passed through a double-band press as aforesaid. In such a material, it will be appreciated, one layer of non-woven fabric is thus located between the two polyester layers. Moreover, it will also be appreciated, other material than a polyester non-woven fabric may be selected for this intermediate layer according to any particular characteristic desired for the material as a whole, bearing in mind of course the overall need to retain sufficient flexibility to ensure that the material will nevertheless be mouldable to the shape of the limb to be supported thereby.

In using the material, firstly it is necessary to soften it by the application of heat. In one preferred use this is effected by immersing the material in a bath of hot water at, say, 70°C; alternatively, if available an oven may be used for the same purpose. Where the material is in sheet form it will normally have been cut to an appropriate size and shape prior to immersion or other form of heating, while if in the form of a strip, e.g. a bandage, it will have been cut to length prior to immersion or other heating. When the material has reached the desired temperature it is then removed from the heat source and applied to the body part of the patient. At this stage although the substance of the material has been heated to a relatively high temperature, in terms of what is tolerable by the patient, because of the relatively low thermal conductivity of the material, it is unlikely that significant discomfort will be caused to the patient by bringing the material into skin contact. Depending upon the particular composition of the material, the material will remain mouldable for a known period, likely to be between one minute and, say, five minutes, thus giving a

"window" for the moulding of the material to the affected body part of the patient. Moreover, depending upon the degree to which the material is heated, and also depending upon to what extent the temperature reached approximates to the crystalline temperature of the material, the material will be self-adherent for at least the initial part of the "window", so that it is possible for the person treating the patient to mould the material to the desired shape and to cause it to adhere to itself, as least as a temporary fixing. In the case of splints for minor sprains, the fixing by self-adherence may be adequate; in the case of casts for fractured limbs, on the other hand, it may be desirable to provide further straps, which may be of the same material, applied subsequently, e.g. by heating locally with a heat gun.

When it is desired to remove the splint or cast, moreover, this may be achieved by again heating to soften the material and then to unwrap it.

MODES FOR CARRYING OUT THE INVENTION

The manufacture of various materials suitable for use in carrying out the invention will now be further described with reference to the following specific examples.

EXAMPLE I

A polyhexamethylene adipate in powder form having a molecular weight calculated at approximately 30,000, a viscosity of approximately 800 Pa.s at 100°C and a particle size range of 0 to 600 microns, which is available from Bostik Limited under the designation Bostik HM5189AE ("Bostik" is a registered trade mark) was mixed in a ratio of 60:40 parts by weight with a cellulosic filler in the form of ground almond shell

having a particle size range of 150 to 400 microns. The mixture was then fed to a hopper through which it was dispensed at a uniform rate onto a lightweight non-woven polyester fabric having weight of 0.18 kg/m^2 supported by the lower belt of a double-band press by which the fabric was advanced beneath the hopper at a uniform rate. "Downstream" of the hopper was arranged an infrared heater by which an initial fusion of the mixture took place, whereafter the thus initially fused composition was covered with a second, similar, non-woven polyester fabric and the laminate was then passed between the upper and lower belts of the double-band press, in which heat was first applied by platens arranged at opposite sides of the belts and heated to a surface temperature of 150°C, whereafter, for a short period, the bands were moved over cooling platens, also arranged at opposite sides of the press, maintained at a temperature of 5°C. Moreover, the gap between the belts progressively tapered towards the outlet end in order thus to consolidate the material to some extent. For consolidating the material further, to a pre-determined gauge, moreover, the material was then passed between two consolidating rollers having also a surface temperature maintained at or about 5°C. The material could thereafter either be stored in roll form (the material still being sufficiently mouldable for this purpose) or be cut into sheets and stacked.

The material thus made had the following characteristics:

Thickness	1.09mm
Weight	1.020 kg/m^2
Density	940 kg/m^3
Modulus (at ambient temperature)	373 MPa.

This material was capable of being used either in strip form, e.g. as a bandage, or in sheet form. Because of its relatively low gauge, it is unlikely that such material in sheet form would be used other than for splinting or perhaps for casting in the case of relatively small body parts.

EXAMPLE II

The same polyhexamethylene adipate and filler as used in Example I was also used in this Example in the same ratio, but in this case the characteristics of the finished material were as follows:

Thickness	2.50mm
Weight	2.855 kg/m^2
Density	1.14 kg/m^3
Modulus	536 MPa

In this case it is unlikely, because of the thickness of the material, that it would be used other than in sheet form, and the material has been found to be useful especially as a casting material. The advantages of this material, as opposed to e.g. plaster of Paris, are essentially ease of application and light weight.

EXAMPLE III

In this Example the ground almond shell filler was replaced by ground olive stone filler of the same particle size range, all the other parameters for the mixture remaining the same. It was found in practice that this material did not significantly differ in physical characteristics from the material of Example I. From this it is concluded that the olive stone filler acts in by and large the same manner with the same effect as the almond shell filler over the whole range of

thicknesses of the material.

EXAMPLE IV

In this case the material was made in a laboratory using a conventional platen press with shims between the platens to determine the thickness to which the material was consolidated. The material in this case, moreover, was a powder mixture in the following ratio by weight:

Polycaprolactone (CAPA 656)	60
Ground almond Shell having a particle size of 300-600 microns	20
Wood Flour have a particle size of 0-400 microns	20

The above mixture was dispersed on release paper and, after dispersion, a further release paper was placed over the mixture and the "sandwich" was placed in the platen press and consolidated at a temperature of 120°C. The finished product had the following physical features:

Thickness	1.43mm
Weight	1.6 kg/m^2
Density	1120 kg/m^3
Modulus	860 MPa.

It will thus be appreciated that in this case a much stiffer material was achieved, which nevertheless could be handled in generally the same manner as the other Examples when softened to a temperature between 55 and 70°C.

EXAMPLE V

In this case a two-ply material is produced. Each ply comprises a layer of a polyhexamethylene adipate in powder form having a molecular weight, viscosity and particle size in a similar range to that of the polyhexamethylene adipate of Example I, but in this case being identified by the designation Bostik HM5512AE. In the case of each layer, furthermore, the polyester was mixed with a cellulosic filler in the form of ground almond shell having a particle size range of 150 to 400 microns. The first ply of said material was produced by depositing a metered polyester:filler layer on a layer of non-woven polyester fabric and thereafter a further layer of the same fabric was placed thereover. The second ply was produced by depositing a metered layer of the polyester:filler mixture on a layer of polyester non-woven fabric. The two plies were then superposed with the fabric surface of the second ply exposed; that is to say with one of the fabric layers of the first ply intermediate the two polyester layers. The "sandwich" was then passed through a double-band press and the process was completed generally in the same manner as described in Example I.

The finished material had the following characteristics:

Thickness (average)	2.64mm
Weight	3125 kg/m^2
Density	1180 kg/m^3
Modulus (at ambient temperature)	706 MPa (width)
	770 MPa (length).

The moisture vapour permeability was 385mg/m^2/hr.

The material exhibited good handling qualities and has been found suitable for use as a casting material.

Claims:

1. The use, as an orthopaedic splinting or casting material, of a material in sheet or strip form comprising

not less than 50% by weight of a polyester having a molecular weight of not less than 10,000 and a viscosity measured at 100°C of at least 30 Pa.s, and

up to 50% by weight of a cellulosic filler,

said material being:

- mouldable at a temperature in the range 55 to 70°C and being self-adherent at such moulding temperature,
- having a weight in the range 0.75 to 4.0 kg/m^2,
- having a density in the range 900 to 1200 kg/m^3, and
- having a modulus, at ambient temperature, of not less than 350 mPa.

2. The use of a material as set out in Claim 1 wherein the polyester is an aliphatic polyester.

3. The use of a material as set out in Claim 1 wherein the polyester is a polymer formed of a cyclic ester.

4. The use of a material as set out in Claim 1 wherein the polyester is a poly-epsilon-caprolactone.

5. The use of a material as set out in Claim 1 wherein the polyester is a polyhexamethylene adipate.

6. The use of a material as set out in Claim 1 wherein the polyester has a molecular weight of at least 30,000 and a viscosity measured at 100°C of at least 600 Pa.s.

7. The use of a material as set out in Claim 1 wherein the polyester:filler ratio is in the order of 60:40.

8. The use of a material as set out in Claim 1 incorporating a fabric layer at or adjacent at least one surface.

9. The use of a material as set out in Claim 8 wherein the fabric of said at least one layer is a non-woven fabric of synthetic material having a melt temperature higher than that of the polyester.

10. The use of a material as set out in Claim 1 wherein the filler is selected from one or a combination of the following:

- ground almond shell having a grain size distribution of 150 to 400 microns,
- ground olive stones having a grain size distribution of 150 to 400 microns, and
- wood flour having a grain size distribution of up to a maximum of 600 microns.

11. An orthopaedic splinting or casting material in sheet or strip form comprising

not less than 50% by weight of a polyester having a molecular weight of not less than 10,000 and a viscosity measured at 100°C of at least 30 Pa.s, and

up to 50% by weight of a cellulosic filler,

said material being mouldable at a temperature in the range 55 to 70°C, being self-adherent at such moulding temperature and having

- a weight in the range 0.75 to 4.0 kg/m^2, preferably 1.25 to 3.75 kg/m^2, more preferably 2.0 to 3.5 kg/m^2,

- a density in the range 900 to 1200 kg/m^3, and
- a modulus, at ambient temperature, of not less than 350 MPa.